DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

1554 5 JUN 10 P2:36

MAY 19 2005

Ref: FDA Docket No. 1998V-0868 Exp.1
Accession Number 9710574

Mr. David J. Costello
Quality System Manager
Cell Robotics, Inc.
2715 Broadbent Parkway, NE
Albuquerque, New Mexico 87107

Dear Mr. Costello:

This is written in response to your April 20, 2005, correspondence requesting extension of the approved variance covering the Model Lasette Finger Perforator, variance number 1998V-0868.

We are approving, in accordance with 21 CFR 1010.4(c)(1), the petition of Cell Robotics, dated April 20, 2005, for an extension of the variance approval from the requirements of 21 CFR 1040.10(f)(3) and 1040.10(f)(4) of the Federal performance standard for laser products to incorporate a remote interlock connector and a key control. This variance extension will allow the introduction into commerce of the Lasette Finger Perforator manufactured by Cell Robotics as identified in paragraph D below under the conditions stated in paragraph F.

A. Variance Number

1998V-0868

B. Effective Date

This variance shall become effective on the date of this letter in accordance with 21 CFR 1010.4(c)(1).

C. Termination Date

This variance shall be terminated 5 years from the date of this letter.

D. Laser Product for Which Variance is Granted

This variance is granted for the Lasette Finger Perforator.

98V-0868

VRA 1

E. Provisions From Which Variance is Granted

The variance is granted from provisions of 21 CFR 1040.10(f)(3) and 1040.10(f)(4) of the performance standard for laser products requiring that each Class IV laser product have a remote interlock connector and have a key control.

All other provisions of 21 CFR 1040.10 and 1040.11 remain applicable to the laser product.

F. Conditions Under Which Variance is Granted

In lieu of the requirements referred to in item E above, the following condition shall apply to the Lasette Finger Perforator manufactured under this variance:

> Both the hinged backstop and lens shield must be in their correct positions, as well as controls set/buttons depressed correctly, in order to have beam emission.

G. Basis for Approval of Variance

CDRH has determined, in accordance with 21 CFR 1010.4(a)(1), that the laser product, the Lasette Finger Perforator, incorporates alternate means for providing radiation safety or protection equal to that provided by products of similar design meeting all the requirements of the standard.

As an alternate for a remote interlock connector the product incorporates a hinged backstop that prevents emission other than when fired at the target area (finger). Since the beam cannot emit unless the backstop has been fully opened and control buttons depressed correctly for each shot, the backstop door is believed to constitute an equivalent degree of safety as a remote interlock connector.

As an alternate for a key control the product incorporates a lens shield that is inserted into the beam path prior to emission and, when removed, fully disables the product. Since the beam cannot emit unless the lens shield is inserted for each shot, the lens shield is believed to constitute an equivalent degree of safety as a key control.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state:

> This product is in conformity with performance standards for laser products under 21 CFR 1040, except with respect to those characteristics authorized by Variance Number 1998V-0868 effective MAY 19 2005

This variance action is available for public disclosure in the Dockets Management Branch, FDA, and a notice of availability will be published in the FEDERAL REGISTER. The variance will remain in effect until the termination date unless the variance is amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Sincerely yours,

Lynne L. Rice
Director
Office of Communication, Education,
and Radiation Programs
Center for Devices and
Radiological Health